**IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION**

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| **IN RE: AMERICAN MEDICAL SYSTEMS INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO**<br><br>**Kathy Dover v. American Medical Systems, Inc.**<br><br>**Case No. 2:16-cv-07903** | **Master File No. 2:12-MD-02325 PRODUCTS LIABILITY LITIGATION**<br><br>**MDL 2325**<br><br>**JOSEPH GOODWIN U.S. DISTRICT JUDGE**<br><br>***Oral Argument Requested*** |

**DEFENDANT AMERICAN MEDICAL SYSTEMS, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT**

## I. INTRODUCTION

Plaintiff has asserted a number of claims against American Medical Systems, Inc. ("AMS"), including strict products liability failure to warn, strict products liability-manufacturing defect, strict products liability design defect, breach of express warranty, breach of implied warranty, fraudulent concealment, constructive fraud, negligent misrepresentation, violation of consumer protection law and negligent infliction of emotional distress. As discussed below, AMS is entitled to summary judgment on all of these claims.

## II. STATEMENT OF UNDISPUTED MATERIAL FACTS

1. Plaintiff is a current resident of Oklahoma, and has been since at least 2003. *Exhibit* 1, Deposition of Kathy Dover, 23:21-24:6.

2. On December 10, 2004, Dr. Nicole Jarvis implanted an AMS SPARC sling ("SPARC") in Plaintiff at the Norman Regional Medical Center, in Norman Oklahoma, *Exhibit* 2, Plaintiff's Fact Sheet, p.5.
3. On February 11, 2019, Plaintiff underwent a mesh trimming procedure which was performed by Dr. Arielle Allen at Lakeside Women's Hospital in Oklahoma City, Oklahoma. *Id*. at p.6. Dr. Allen testified that the mesh exposure was asymptomatic and that there was no medical reason to trim the mesh. *Exhibit* 3, Deposition of Dr. Ariella Allen, 49:10-13; 50:6-12.
4. Plaintiff claims to have experienced recurrent incontinence, dyspareunia, bladder infections and an abscess as a result of implantation of the SPARC. *Exhibit* 1, Deposition of Kathy Dover, 34:13-15 -35:5.
5. At the time she implanted the SPARC in Plaintiff, Dr. Jarvis was aware of the risk of all of the complications of which Plaintiff complains. *Exhibit* 4, Deposition of Dr. Nicole Jarvis, 23:11-20; 24:14-19; 25:7-9; 25:19-21; 26:5-18; 27:17-19; 28:2-6. Moreover, Dr. Jarvis did not rely on the Instructions For Use for the SPARC to inform her of the risks of the SPARC. *Id.* at 29:25-30:7.
6. Prior to have the SPARC implant procedure, Plaintiff had not seen any materials or advertisements concerning the SPARC, nor had she had any communication with AMS. *Exhibit* 1, Deposition of Kathy Dover, 58:18-59:7.

## III. STANDARD OF REVIEW

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to summary judgment as a matter of law. Fed. R. Civ. P. 56(a; *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). In considering a

motion for summary judgment, the court should not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249 (1986). Instead, the court should draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 58788 (1986). The nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor [.]" *Anderson,* 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex, 477* U.S. at 322-23. The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson, 477* U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.,* 818 F.2d 1126, 1128 (4th Cir. 1987).

## IV. CHOICE OF LAW

Plaintiff filed her claim directly into this MDL. Therefore, the Court consults the choice-of-law rules of the state where the Plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.,* 2014 WL 202787 at *4 (S.D.W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, the court will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the Plaintiff was implanted with the product."). Plaintiff's SPARC was implanted in Oklahoma. Thus, the choice-of-law principles of Oklahoma guide the court's choice-of-law analysis.

Oklahoma has adopted the general rule of the Restatement (Second) of Conflict of Laws, "that the rights and liabilities of parties with respect to a particular issue in tort shall be determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties." *Brickner v. Gooden*, 525 P.2d 632, 637 (Okla. 1974). Under this significant relationship test, the following factors should be considered and "evaluated according to their relative importance with respect to a particular issue:

1) the place where the injury occurred,

2) the place where the conduct causing the injury occurred,

3) the domicile, residence, nationality, place of incorporation and place of business of the parties, and

4) the place where the relationship, if any, between the parties occurred."

*Brickner*, 525 P.2d at 637.

Applying the test to the present case, Oklahoma has the most significant contacts to this controversy. Plaintiff resides in Oklahoma and was an Oklahoma resident at the time of her implants. Plaintiff allegedly suffered her injuries in Oklahoma, and she has received treatment for her alleged injuries in Oklahoma. There is no relationship between Plaintiff and AMS, other than the fact that Plaintiff was implanted with a product manufactured by AMS. Thus, to the extent that Plaintiff's receipt of the AMS product could be considered to affect the "place where the relationship . . . occurred" factor, such relationship arose in Oklahoma where the AMS product was implanted in Plaintiff. Accordingly, Oklahoma law applies to Plaintiff's substantive claims.

## V. ARGUMENT

### A. Under Oklahoma's Learned Intermediary Doctrine, Plaintiff Cannot Satisfy Her Burden Of Proving That Any Alleged Failure To Warn Proximately Caused Her Injuries

#### 1. In Oklahoma, a Manufacturer's Duty to Warn is Defined by the Learned Intermediary Doctrine.

Under Oklahoma's learned intermediary doctrine, prescription drug and medical device manufacturers[1] are not required to provide warnings directly to patients for whom their products are prescribed. Instead, the manufacturer discharges its duty to warn by warning the prescribing physician. *Eck v. Parke, Davis & Co*., 256 F.3d 1013, 1017 (10th Cir. 2001) (citing *Edwards v. Basel Pharms.*, 933 P.2d 298, 300 (Okla. 1997)). According to the Tenth Circuit, this is because:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprize the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

*Edwards*, 933 P.2d at 300-01 (emphasis added by the Tenth Circuit) (quoting *Wooderson v. Ortho Pharm. Corp.,)* 681 P.2d 1038, 1052 (Kan. 1984)).

Beyond the adequacy of the warnings provided to the physician, a plaintiff is required to prove so-called "warnings causation"; in other words, even if a plaintiff can establish that the manufacturer failed to provide her physician with adequate warnings, she must further establish

[1] The learned intermediary doctrine applies to prescription drugs, as well as medical devices. *See, e.g., Tansy v. Deaconess Corp.*, 890 P.2d 881, 886 (Okla. 1994) (applying learned intermediary doctrine to penile implant); *McKee v. Moore*, 640 P.2d 21 (Okla. 1982); (applying doctrine to IUD).

proximate causation by showing that a different warning would have changed her physician's prescribing decision. *Eck,* 256 F.3d at 1018. In Oklahoma, a plaintiff is entitled to a rebuttable presumption that her physician would have "read and heeded" an adequate warning. *Id* at 1018-19 (citing *Cunningham v. Charles Pfizer & Co*., 532 P.2d 1377, 1382 (Okla. 1974) and *Woulfe v. Eli Lilly & Co.,* 965 F. Supp. 1478, 1483 (E.D. Okla. 1997)[2] The presumption disappears if the prescribing physician never read the warnings the manufacturer provided. *Daniel v. Ben E. Keith Co.*, 97 F.3d 1329, 1333 (10th Cir. 1996) (applying Oklahoma law). Moreover, the manufacturer can rebut the presumption by establishing that a different warning would not have changed the physician's prescribing decision. See *Eck*, 256 F.3d at 1019. Then, "the burden shifts rather heavily back upon the [plaintiff]." *Id*. To satisfy this burden and reach the jury on a failure-to warn claim, the plaintiff must "either discredit the physicians' testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to warn was the proximate cause of [her] injuries." *Id*. (internal citations omitted). In other words, the plaintiff must "demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product" for her. *Id*

In this case, as explained below, Plaintiff cannot satisfy her burden of proving proximate causation, because at the time she implanted the SPARC in Plaintiff, Dr. Jarvis was aware of the risks of all of the complications allegedly experienced by Plaintiff. Moreover, on the undisputed record, no different or additional warning would have altered Dr. Jarvis decision to implant the SPARC in Plaintiff.

[2] In this context, "heed" means only that the learned intermediary would have incorporated the additional risk into his risk/benefit calculus. *Eck,* 256 F.3d at 1021.

**2. Plaintiff's Failure-to-Warn Claims Fail Because Dr. Jarvis Was Aware of The Risks of All of Plaintiff's Alleged Injuries Before She Performed Plaintiff's SPARC Implant Procedures**

Plaintiff claims that the SPARC didn't work, causing a recurrence of her stress urinary incontinence. She also claims that the SPARC caused her to suffer dyspareunia, bladder infections and an abscess.

> Q So I'm sure -- so to make sure that I've got everything, you claim that the mesh has damaged you because you're leaking urine again, so it didn't work?
> A Right.
> Q Okay. And the mesh has damaged you because it has caused you to have pain with intercourse?
> A Yes.
> Q And you're claiming the mesh has damaged you because you have had bladder infections?
> A Yes.
> Q And you claim that the mesh has injured you because you had an abscess that ruptured; correct?
> A Yes.
> Q Okay. Anything else?
> A No.

*Exhibit* 1, Deposition of Kathy Dover, 34:13-35:5.

Dr. Jarvis' deposition testimony establishes beyond dispute that she was aware of the risk of all of these complications when she implanted Plaintiff with the SPARC:

> Q. You indicated that all surgeries have risks. I'd like to talk about the risks associated with placement of the SPARC sling.
> Was failure of the device a risk of the SPARC sling?
> A. By "failure of the device," do you mean that it didn't work to eliminate the stress incontinence for which it was used?
> Q. Yes, ma'am.
> A. Yes, that's possible.
> ***
> Q. Was infection a risk of placement of the SPARC?

A. Yes.
Q. And would that include urinary tract infections and bladder infections?
A. Yes.
***
Q. Well, would you say, then, that infection and abscess were a risk of the placement of the SPARC?
A. Yes.
***
Q. Okay. Was erosion a risk of placement of the SPARC?
A. Yes.
***
Q. And some people do. So the risk of erosion of the SPARC through the vaginal vault was a risk of placement of the SPARC?
A. Yes.
Q. Was recurrence of stress urinary incontinence a risk of placement of the SPARC?
A. I would call that the same as the first thing you said, which was failure of the device.
Q. Okay.
A. So yes.
Q. So yes?
A. Uh-huh.
Q. I'm sorry. Yes?
A. Yes.
***
Q. So dyspareunia was a risk of placement of the SPARC, correct?
A. Correct.
***
Q. And is it fair to say that, with respect to the risks that you've acknowledged were risks of placement of the SPARC, that you were aware of those risks when you placed the SPARC in Ms. Dover?
A. Yes.

*Exhibit* 4, Deposition of Dr. Nicole Jarvis, 23:11-20; 24:14-19; 25:7-9; 25:19-21; 26:5-18; 27:17-19; 28:2-8.

As courts across the country have confirmed, no alleged deficiency in AMS's warnings could be the proximate cause of Plaintiff's alleged injuries, because Dr. Jarvis was aware, before Plaintiff's implant surgery, of the risk of all of the injuries Plaintiff claims to have suffered. *See,*

*e.g., Weitz v. Lovelace Health Sys., Inc.*, 214 F.3d 1175, 1182 (10th Cir. 2000) (acknowledging "the common sense proposition that a duty to warn does not arise where the danger is known."); *Kirsch v. Picker Intern, Inc.*, 753 F.2d 670 (8th Cir. 1985) (even if manufacturer failed to warn physician of risks associated with use of x-ray equipment, that failure could not be the cause of the patient's injuries where physician already was aware of the risks); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (where doctor had full knowledge of risk allegedly not warned of, alleged failure to warn could not be the proximate cause of alleged injuries); *Plumber v. Lederle Laboratories*, 819 F.2d 349, 358-59 (2d Cir. 1987) holding that, as a matter of law, there could be no proximate cause when the physician testified that, at the time he vaccinated the plaintiff's granddaughter, he knew of the information about the risks of contact polio that the plaintiff claimed should have been included in the vaccine's package insert); *Stanback v. Parke Davis & Co.*, 675 F.2d 642, 645 (4th Cir. 1981) (summary judgment upheld on the plaintiff's failure to warn claim where treating physician testified that he knew of the risk of Guillain-Barre Syndrome associated with the flu vaccine at the time he vaccinated the plaintiff); *Pustejovsky v. Wyeth, Inc.*, 2009 WL 3336032 at *3 (N.D. Tex., September 4, 2009) (because prescribing physician was aware of possible risks of drug but decided to prescribe it to the plaintiff anyway, the allegedly inadequate warning was not the producing cause of the plaintiff's injury); *Hall v. Merck, Sharp & Dohme*, 774 F. Supp. 604, 607 (D. Kan. 1991) ("Where it is uncontroverted that the prescribing physician is aware of the risks associated with a drug, courts have consistently held that a drug manufacturer is entitled to summary judgment."); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (under learned intermediary doctrine "[i]f the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury.").

Moreover, AMS has rebutted the heeding presumption. It is undisputed that, despite the fact that Dr. Jarvis was aware of the risk of all complications that Plaintiff claims to have experienced, he nevertheless implanted the SPARC in Plaintiff. Thus, no warning about the risk of these complications would have changed Dr. Jarvis' prescribing decision.

In sum, the facts are undisputed and the law is clear. Before Dr. Jarvis implanted the SPARC in Plaintiff, she was aware of the risks of the all of the complications that Plaintiff claims to have experienced. Accordingly, as a matter of law, Plaintiff cannot establish that any alleged failure to warn was the proximate cause of her injuries, and AMS is entitled to summary judgment on Plaintiff's failure-to-warn claims.

**3. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Failure To Warn For The Additional Reason That Dr. Jarvis Did Not Rely On The IFU For The SPARC To Inform Her Of The Risks Of The SPARC**

In this case, it is undisputed that Dr. Jarvis did not rely on the IFU for the SPARC to inform her of the risks of the SPARC. In that regard, Dr. Jarvis testified as follows:

> Q. And that's fair, but my question is, you had indicated that you were aware of the risks of placement of the SPARC without having to read these instructions we've marked as Exhibit 3. And so my question is, is it fair to say, then, that you did not rely on the Instructions For Use for the SPARC to inform you of the risks of placement of the SPARC?
> A. Correct.

*Exhibit* 4, Deposition of Dr. Nicole Jarvis, 29:25-30:7.

As this Court has stated in granting summary judgment for the defendant on a plaintiff's failure to warn claims, "if a doctor did not read the warning, or if a doctor read but did not rely on the warning, then the chain of causation is broken and a plaintiff cannot establish proximate causation." *Howard v. Boston Sci. Corp*. No. 2:12-cv-04145, 2016 WL 1436683, *4 (S.D. W.V.

April 11, 2016). Thus, the fact that Dr. Jarvis did not rely on the IFU for the SPARC, or warnings contained therein, breaks the chain of causation between the alleged insufficient warnings and Plaintiff's asserted injuries.

Other courts are in accord. For example, in *Mampe v. Ayerst Laboratories*, 548 A.2d 798 (D.C. App. 1988), the trial court granted summary judgment in favor of the drug manufacturer on plaintiff's failure to warn claim. On appeal, the court noted that the prescribing physician, in his deposition, "specifically stated on several occasions that he did not rely on the manufacturer's warnings as a source of information about the possible adverse reactions to [the drug at issue]." *Mampe*, 548 A.2d at 802. The appellate court concluded that "this testimony establishes beyond dispute that his decision to prescribe Antabuse for Mrs. Mampe would not have been affected in the least by the communication of an adequate warning (assuming that Ayerst's warning was inadequate)." Id. Thus, the appellate court affirmed summary judgment in favor of the manufacturer on the failure to warn claim because plaintiffs "could not prove that the alleged inadequacy in Ayerst's warning was a proximate cause of her injuries and the trial court was correct in granting summary judgment for Ayerst." *Id.* *See* also, *Wollam v. Wright Medical Group, Inc*., No. 1:10-cv-3104-DME-BNB, 2012 WL 4510695, (D. Colo. September 30, 2012) (where implanter of medical device testified that he did not read or otherwise rely on manufacturer's warnings, plaintiff could not establish that failure to warn prior to implant of device was proximate cause of plaintiff's injury); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 996 (C.D. Cal. 2001) (because prescriber did not rely on warnings from drug manufacturer, plaintiff could not prove that adequate warnings would have changed prescriber's decision to prescribe drug to plaintiff); *Pustejovsky v. Pliva, Inc*., 623 F.3d 271, 277 (5th Cir. 2010) (because physician did not

recall ever reading the warning in package insert, allegedly inadequate warnings could not be the proximate cause of his patient's injuries).

Plaintiff cannot meet her burden under Oklahoma law to establish that a failure to warn was the proximate cause of her injuries because Dr. Jarvis testified that she did not rely on the IFU for the SPARC to inform her of the risks of the SPARC. *Eck, supra*. On this basis alone, AMS is entitled to summary judgment on plaintiff's claim for failure to warn.

**4. AMS Is Entitled To Summary Judgment On All Claims Grounded In The Failure To Warn Claim**

Plaintiff cannot sustain her claims for breach of express and implied warranties, fraudulent concealment, constructive fraud, negligent misrepresentation and violation of consumer protection laws or gross negligence. All of these claims find their genesis in Plaintiff's claim of failure to warn, and, accordingly, all claims fail as a matter of law. As this Court held in *Bellew v. Ethicon*, the Plaintiff cannot evade the learned intermediary doctrine by packaging her failure to warn claims under different doctrines. *Bellew v. Ethicon*, No. 2:13-cv-22473, 2014 WL 6886129, at *5-6 (S.D. W.Va. Nov. 24, 2014) (dismissing claims for fraud, fraudulent concealment, negligent misrepresentation, breach of warranty, and Arizona Consumer Fraud Act); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 745 (S.D. W.Va.) (awarding judgment to Ethicon on fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, and breach of warranty claims under Illinois law). That is because "[i]f the learned intermediary doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action…then the doctrine would be rendered meaningless." *Huskey*, 29 F.Supp.3d at 744 (quoting *In re Norplant Contraceptive Products Liab. Lit.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997). For the same reasons, AMS is entitled to summary judgment on all of these claims.

Thus, based on the foregoing, because AMS is entitled to summary judgment on Plaintiff's failure to warn claim, AMS is further entitled to summary judgment on Plaintiff's claims for breach of implied and express warranty, fraudulent concealment, constructive fraud, negligent misrepresentation and violation of consumer protection laws.

### B. AMS Is Entitled to Summary Judgment on Plaintiff's Claims For Violation Of Consumer Protection Laws, Breach Of Express And Implied Warranties And Fraudulent Concealment for Additional Reasons.

Beyond the fact that Plaintiff's claims for violation of consumer protection laws, breach of express and implied warranties and fraudulent concealment fail as re-packaged failure to warn claims, and AMS is entitled to summary judgment on these claims for additional reasons. Plaintiff's failure to warn claim. However, as discussed below, additional and independent reasons exist for granting AMS summary judgment on these claims.

#### 1. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Violation Of The Oklahoma Consumer Protection Act

In her Short-Form Complaint, Plaintiff asserts a claim for "violation of consumer protection laws." In Oklahoma, the relevant statute is the Oklahoma Consumer Protection Act ("OCPA") 15 O.S. § 751, et seq. The OCPA contains a "safe harbor" that exempts from its coverage "[a]ctions or transactions regulated under laws administered by the Corporation Commission or any other regulatory body or officer acting under statutory authority of this state of the United States . . . ." O.S. § 754(2) ("Section 744(2)").

The Northern District of Oklahoma's decision in *Childs v. Unified Life Ins. Co.*, 2011 WL 1045533 (N.D. Okla. Mar. 17, 2011), is instructive. In *Childs*, the plaintiff claimed that the defendant improperly sold her a dental insurance plan. After finding that the dental plan was regulated by the Oklahoma Insurance Code and the Insurance Commissioner, the court held that "dismissal of Plaintiff's OCPA claim [is] proper" pursuant to Section 754(2). *Id.* at *8.

The OCPA's exemption provision is not limited to insurance actions. For example, in *Estate of Hicks ex rel. Summers v. Urban East, Inc.*, 92 P.3d 88 (Okla. 2004), the Oklahoma Supreme Court sustained the trial court order dismissing Plaintiff's OCPA claim after finding that "[t]he 'action or transaction' in the case at bar [which] involves the services and level of care alleged to have been wrongfully represented to Plaintiff's decedent . . . is regulated under laws administered by Oklahoma Department of Health, as mandated by the Nursing Home Care Act." *Id.* at 95. Therefore, the Court concluded that Plaintiff's claim fell "squarely within the exemption of the Oklahoma Consumer Protection Act found at § 754(2)." *Id.*

Here, Plaintiff's claim falls squarely within Section 744(2)'s exemption, because it relates to a product cleared by the United States Food and Drug Administration, which promulgates comprehensive regulations governing every facet of the design of prescription medical products, the marketing of those products, and the warnings included with the products.[3] Accordingly, AMS is exempt from liability and, entitled to summary judgment on Plaintiff's "violation of consumer protection laws" claim.

**2. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Breach Of Express Warranty**

Under Oklahoma law, a plaintiff cannot state a claim for breach of an express warranty unless the express warranty was "part of the basis of the bargain" when the product was acquired. *See* 12A O.S. § 1(a), (b) and (c). It is undisputed that Plaintiff did not see any written materials concerning the SPARC:

> Q Prior to having the Spark implanted had you ever seen any written materials concerning the Spark sling?

[3] *E.g. Marcus v. Forest Laboratories, Inc.*, No. 13-11343-NMG, 2014 WL 866571 (D. Mass. March 5, 2014) (holding that consumer fraud claims based on overrepresentation of an antidepressant's efficacy fell under California safe harbor provisions).

A No.
Q Prior to having the implant surgery had you ever had any communications with AMS?
A No.
Q Prior to having the implant surgery had you ever seen any kind of advertisements on TV or otherwise about the Spark sling?
A No.
Q Prior to having the implant surgery had you ever seen any kind of materials put out by AMS concerning the Spark sling?
A No.

*Exhibit* 1, Deposition of Kathy Dover,

Accordingly, no "express warranty" could possibly have been part of the "basis of the bargain" when Plaintiff acquired her SPARC and therefore AMS is entitled to summary judgment on Plaintiff's breach of express warranty claim for this additional reason.

**3. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Breach Of Implied Warranty**

Under Oklahoma law, "[i]n a products liability action, breach of implied warranty is no longer an appropriate remedy except as provided in the Uniform Commercial Code." *Alexander v. Smith & Nephew*, 98 F. Supp. 2d 1310, 1322 (N.D. Okla. 2000); *see also, Kirkland v. General Motors, Corp.*, 521 P.2d 1353, (Okla. 1974); *Moss v. Polyco, Inc.*, 522 P.2d 622 (Okla. 1974). Because this case sounds in products liability, Plaintiff cannot assert a claim for breach of implied warranty under Oklahoma law, and this claim should be dismissed.

**4. Plaintiff's Claim For Fraudulent Concealment Should Be Dismissed**

In her Short Form Complaint, Plaintiff asserts a claim for fraudulent concealment. Under Oklahoma law, fraudulent concealment is not an independent cause of action, and therefore, it is not a claim upon which relief may be granted. *McAlister v. Ford Motor Co.*, No. CIV-14-1351-D, 2015 WL 4775382 (W.D. Okla. August 13, 2015) is instructive. In *McAlister*, defendant Ford

Motor Co. filed a motion to dismiss plaintiffs' claim for fraudulent concealment, among others, for failure to state a claim.. Addressing the motion to dismiss the fraudulent concealment claim and applying Oklahoma law, the Court stated that "[F]raudulent concealment is typically raised as a response to a statute of limitations defense, rather than as a separate claim for relief." *McAlister*, 2015 WL 4775382 at *3. (Quoting *AG Equipment Co. v. AIG Life Ins. Co.*, No. 07-CV-0556-CVE-PJC, 2008 WL 4570319, *3 (N.D. Okla. October 10, 2008). Noting that the plaintiff acknowledged that "fraudulent concealment is not a cause of action" in Oklahoma, the Court granted defendant's motion to dismiss the claim for fraudulent concealment. The same result is warranted here.

**C. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Manufacturing Defect**

In Oklahoma,

> A product is defective in manufacture if it "deviates in some material way from its design or performance standards. The issue is whether the product was rendered unsafe by an error in the manufacturing process." Errors in the process are often established by showing that a product, as produced, failed to conform with the manufacturer's specifications.

*Wheeler v. HO Sports, Inc., 232 F.3d 754, 757 (10th Cir. 2000) (citations omitted). See also, Manous v. Mylan Pharmaceuticals, Inc., 982 F.Supp.2d 1262, 1284 (W.D. Okla 2013).*

To establish a manufacturing defect under Oklahoma law, Plaintiff must offer a theory as to the cause of the defect, going beyond "a mere assertive statement that the defect occurred during manufacturing." *Kimbell v. Zenith Radio Corp.*, 555 P.2d 590, 593 (Okla. 1976). Moreover, expert testimony is required to establish a claim for manufacturing defect. For example, in *Manous*, *supra*, Plaintiff brought an action against a manufacturer of a fentanyl patch, claiming a manufacturing defect in the patch. The defendant manufacturer sought summary judgment on the

manufacturing defect claim, finding that the Plaintiff "cannot proceed to trial, because he is missing an expert to explain his contentions regrading to defective manufacture of the parties." *Manous*, 982 F.Supp.2d at 1283.

In this case, Plaintiff has failed to adduce any evidence, much less the expert testimony or opinions required under Oklahoma law, that there was any manufacturing defect in the SPARC that was implanted in her. None of Plaintiff's expert reports addresses any manufacturing defect in either product. AMS is therefore entitled to summary judgment on Plaintiff's claim for manufacturing

**D. AMS Is Entitled To Summary Judgment On Plaintiff's Claim For Negligent Infliction Of Emotional Distress**

In her Short Form Complaint, Plaintiff asserts a claim for negligent infliction of emotional distress. Like a claim for fraudulent concealment, a claim for negligent infliction of emotional distress is not an independent tort in Oklahoma. *Krazewski v. Baptist Medical Center of Oklahoma, Inc.*, 1996 OK 141, 916 P.2d 241, 242, n.1 ("Unlike a cause of action for intentional infliction of emotional distress, negligent infliction of emotional distress is not an independent tort."); *Lockhart v. Loosen*, 1997 OK 103, 943 P.2d 1074, 1081 ("Under Oklahoma's jurisprudence the negligent causing of emotional distress is not an independent tort, but is in effect the tort of negligence.") (footnotes omitted); *Mason v. State ex rel. Board of Regents*, 2001 OK CIV APP 33, 23 P.3d 964, 969 ("negligent infliction of emotional distress is not an independent tort"); *Wilson v. Michael*, 303 F.3d 1207, 1213 (10th Cir. 2002) (recognizing that "Oklahoma courts say that negligent infliction of emotional distress is not an independent tort, but is in effect the tort of negligence,"

and therefore holding that "[a] Plaintiffs therefore cannot proceed on a negligent infliction of emotional distress theory of liability separate from negligence.").

Thus, AMS is entitled to summary judgment on Plaintiff's claim for negligent infliction of emotional distress.

## VI. CONCLUSION

On the undisputed record, Plaintiff cannot sustain her claims of failure to warn, manufacturing defect, design defect, breach of express warranty, breach of implied warranty, fraudulent concealment, constructive fraud, negligent misrepresentation, violation of consumer protection laws and negligent infliction of emotional distress. No disputed issues of material fact remain, and AMS is entitled to summary judgment on all of these claims.

Respectfully submitted,

*/s/ Erik W. Legg, Esq.*
Michael J. Farrell, Esquire (WVSB # 1168)
Erik W. Legg, Esquire (WVSB # 7738)
**FARRELL, WHITE & LEGG PLLC**
914 Fifth Avenue
Huntington, West Virginia 25701
(304) 522-9100
mjf@farrell3.com
ewl@farrell3.com

*/s/ Stephen J. McConnell, Esq.*
Stephen J. McConnell, Esq. (PA Bar # 80583)
Barbara R. Binis, Esq. (PA Bar # 62359)
Rachel B. Weil, Esq. (PA Bar # 49844)
**REED SMITH LLP**
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, Pennsylvania 19103
(215) 851-8100
smcconnell@reedsmith.com
bbinis@reedsmith.com
rweil@reedsmith.com

*Attorneys for Defendant American Medical Systems, Inc.*

Dated: August 14, 2019

**CERTIFICATE OF SERVICE**

I hereby certify that on August 14, 2019, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*/s/ Stephen J. McConnell*